1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1214 which seeks to permit the use of nicotinamide riboside chloride as a form of niacin in food for special medical purposes (FSMPs). The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting[1], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation amending the table to section S29—20 of the Code to include 'nicotinamide riboside chloride' in the list of permitted forms of niacin that may be added to FSMPs. The draft variation also amends Schedule 3 to include a specification for nicotinamide riboside chloride in that Schedule.

The amendments in the draft variation permit the use of nicotinamide riboside chloride as a form of niacin in FSMPs in accordance with the Code.

3. Documents incorporated by reference

The variation in this instrument does not incorporate any documents by reference.

However, the instrument will vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017); the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition); and the Commission Regulation (EU) No 231/2012.

4. Consultation

[1] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum). The Forum name change took effect on 21 February 2021 following a decision by Ministers.

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1214 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 22 April 2021 for a four week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for the voluntary addition of a nutritive substance to food (OBPR correspondence dated 16 April 2013, reference 14943). This standing exemption was provided as permitting an additional nutritive substance to food is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Schedule 3.

Sub item [1.1] inserts a reference to 'nicotinamide riboside chloride' and its relevant provision into the table to S3—2(2), in alphabetical order. The table to S3—2(2) lists certain substances and their 'relevant provisions' i.e. provisions indicating where specifications for the listed substances are located in Schedule 3.

Sub item [1.2] inserts new section S3—44 into Schedule 3, which contains the new specification for 'nicotinamide riboside chloride'.

Item [2] amends Schedule 29 by omitting the existing entry of 'Niacin' in the table to section S29—20 and substituting it with a new entry. The new entry for Niacin lists 'nicotinamide riboside chloride' as one of two permitted forms of Niacin that may be added to FSMPs. The effect of this amendment is that nicotinamide riboside chloride will be a permitted form of niacin that may be added to FSMPs in accordance with the Code.

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